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| 10/509,552 | 06/09/2005 | Per Gisle Djupesland | 44508-137 | 5912 |
| 21890 | 7590 | 10/28/2008 | EXAMINER | |
| PROSKAUER ROSE LLP PATENT DEPARTMENT 1585 BROADWAY NEW YORK, NY 10036-8299 | | | OSTRUP, CLINTON T | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/509,552

Applicant(s)

DJUPESLAND, PER GISLE

Examiner

CLINTON OSTRUP

Art Unit

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-16, 18-31, 35, 36 and 38-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-16, 18-31, 35, 36 and 38-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 May 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7/9/08.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This Office Action is in response to the amendment filed 7/9/08. As directed by the amendment, claims 2, 17, 32, 34, and 37 have been cancelled and claims 1, 4, 6, 16, 18, 28, 31, 33, 35-36, 38, and 40 have been amended. Thus, claims 1, 3-16, 18-31, 35-36, and 38-43 are pending in this application.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, "the mouthpiece which includes a flexible member which is deflectable on exhalation" claimed in claims 38-43 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

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Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 28 and 35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 6,715,485. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are all drawn to nasal delivery devices for delivering a substance to a nasal airway comprising a nasal delivery unit, a mouthpiece and a gas supply.

Claim 28 is drawn to a "nasal delivery device for delivering substance to a nasal airway of a subject, comprising: a mouthpiece through which a subject in use exhales to cause closure of the oropharyngeal velum of the subject; at least one delivery unit for delivering substance to a nasal airway of the subject on exhalation by the subject; and a gas supply unit for cycling a pressure in the nasal airway of the subject on exhalation by the subject."

Claim 35 is drawn to a "nasal delivery device for delivering substance to a nasal airway of a subject, comprising: a mouthpiece through which a subject in use exhales to cause closure of the oropharyngeal velum of the subject; at least one delivery unit for delivering substance to a nasal airway of the subject on exhalation by the subject; and a gas supply unit for alternately delivering and withdrawing a volume of gas through the nasal airway of the subject on exhalation by the subject, such as to cause entrained substance to be flushed in alternate directions therethrough.

Claim 6 of 6,715,485 comprises a nasal delivery device comprising a closure unit that comprises a mouthpiece for causing the closure of the oropharyngeal velum of the subject, a delivery unit for delivering a substance to the nostrils of a subject, and a gas supply unit that is configured to deliver a gas flow; therefore, all the structural limitations of instant claims 28 and 35 are previously claimed in claim 6 of 6,715,485.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 3-16, 18-23, 26-31, 33, 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Djupesland et al., (WO 01/97689 A1) and further in view of Alving et al (6,019,100).

Djupesland discloses a nasal delivery device (figures 5A-5D) for delivering a substance (exhaled gas) to a nasal airway of a subject, comprising: first (tube with 311 attached) and second (tube with 312 attached) nosepiece units, each including a nosepiece (311, 312) for fitting to respective nostrils of a subject; at least one substance supply unit (330) for supplying substance for delivery to the nasal airway of the subject; a valve unit (335 in figure 5B) for fluidly connecting the at least one substance supply unit to one of the nosepiece units ; and a mouthpiece (310) through which the subject in use exhales to cause closure of the oropharyngeal velum of the subject during delivery of substance. See: page 17, line 15 - page 18, line 7.

Although Djupesland discloses a three way valve connected to the substance supply unit, it lacks the detailed description of the valve being used for selectively fluidly connecting a supply unit to respective nose piece units. Alving teaches using a three way valve to alternatively connect tubes to the nostrils of a user. See: col. 6, lines 1-4.

It would have been obvious to one having ordinary skill in the art to have modified the three way valve connection disclosed by Djupesland to form a connection that selectively connects to either nosepiece, as taught by Alving, in order to obtain a device that would selectively deliver a gas substance to either nostril of a user.

Regarding claim 3, Djupesland discloses a gas supply channel (inside of tube connecting mouthpiece (310) to nosepiece (311) for supplying a gas flow for entraining substance supplied by the at least one substance supply unit (330).

Regarding claim 4, Djupesland discloses a mouthpiece (310) that is fluidly connected to the gas supply channel, whereby the gas flow is an air flow developed by an exhalation breath of the subject. See: figures 5A-5D.

Regarding claim 5, Alving teaches a gas supply unit (4) which is fluidly connected to the gas supply channel for delivering a gas flow through the gas supply channel.

Regarding claim 6, Alving discloses a gas supply unit (4) and Djupesland discloses an exhalation breath actuatable unit (a resistor) which is fluidly connected to the mouthpiece (via the tube (340) such as to be actuated on exhalation by the subject.

Regarding claim 7, Alving discloses a valve unit (See: col. 6, lines 1-4) that is configured alternately fluidly to connect one of the nosepiece units (tube with 311 attached) to the at least one substance supply unit (330) and vent the other of the nosepiece units (tube connected to 312), such that, where the gas flow is at a driving pressure which is such as to cause the gas flow to flow around the posterior margin of the nasal septum and through the nasal airway, the gas flow delivered through the one nosepiece unit is vented through the other nosepiece unit. See: figures 5A-5D.

Regarding claim 8, Djupesland discloses at least one flow resistor (320 in figure 5B) to which the other nosepiece unit (tube connected to 12) is vented.

Regarding claim 9, Djupesland discloses a flow resistor has a fixed flow resistance (page 7, lines 9-11) for providing a fixed flow resistance to the gas flow.

Regarding claims 10-11 Djupesland discloses that different resistors with dimensions suited to produce the desired flows at the same positive pressure gradient are useful for avoidance of possible pressure related changes in NO output. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted one known resistor for another to produce the desired flow at the same pressure gradient as taught and suggested by Djupesland. See: page 5, lines 4-8.

Regarding claim 12, Alving teaches a control unit (7) that can be used for controlling the valve unit to alternate delivery of a substance through the nosepiece units.

Regarding claim 13, Djupesland discloses a single substance supply unit (330) that can be used to supply a substance alternately to respective ones of the first and second nosepiece units.

Regarding claim 14, Alving discloses a first (3A) and second (3B) substance supply units for supplying substance for delivery to respective ones of the first (tube with 311 attached) and second (tube with 312 attached) nosepiece units.

Regarding claim 15, Djupesland discloses a three-way valve which Alving teaches can function in the same manner as two one way valves to selectively connect a first and second nosepiece unit and it would have been obvious to a skilled artisan to chose a three way valve over two one way valves in order to for a more compact valve system that is easier to manipulate.

Regarding claim 16, Djupesland discloses a method of delivering substance to a nasal airway of a subject by fitting first (311) and second (312) nosepiece units to respective nostrils of a subject; and exhaling through a mouthpiece (310) during delivery of substance to cause closure of the oropharyngeal velum of the subject and Alving teaches delivering substance alternately through respective ones of the nosepiece units.

Regarding claim 18, Djupesland discloses a substance (CO₂) that is delivered in a gas flow.

Regarding claim 19, Djupesland discloses a gas flow as air flow developed by an exhalation breath of the subject.

Regarding claim 20, Alving teaches providing a gas flow that is separate to an exhalation breath of the subject.

Regarding claim 21, Alving teaches a substance that is delivered alternately to the nosepiece units and Djupesland discloses that when the gas flow is at a driving pressure which is such as to cause the gas flow to flow around the posterior margin of the nasal septum and through the nasal airway, the gas flow delivered through the one nosepiece unit (311) is vented through the other nosepiece unit (312). See: figures 5A-5D.

Regarding claim 22, Djupesland discloses the gas flow is vented through a flow resistor (320 of figure 5B & 5C).

Regarding claim 23, Djupesland discloses a flow resistor that has a fixed flow resistance (page 7, lines 9-11) and provides a fixed flow resistance to the gas flow.

Regarding claims 24-25 Djupesland discloses that different resistors with dimensions suited to produce the desired flows at the same positive pressure gradient are useful for avoidance of possible pressure related changes in NO output. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted one known resistor for another to produce the desired flow at the same pressure gradient as taught and suggested by Djupesland. See: page 5, lines 4-8.

Regarding claim 26, Djupesland discloses a substance (CO₂) that is supplied from a single substance supply unit (330).

Regarding claim 27, Alving teaches a substance that is supplied to the first and second nosepiece units (figure 2) from respective ones of first (3A) and second (3B) substance supply units.

Regarding claim 28, Djupesland discloses a nasal delivery device (figures 5A-5D) for delivering substance to a nasal airway of a subject, with a mouthpiece (310) through which a subject in use exhales to cause closure of the oropharyngeal velum of the subject; and Alving teaches at least one delivery unit (3A & 3B) for delivering substance to a nasal airway of the subject on exhalation by the subject; and a gas supply unit (4) for cycling a pressure in the nasal airway of the subject on exhalation by the subject.

Regarding claim 29, the gas supply unit (4) is a ventilator and is therefore configured to provide an alternating pressure in the nasal airway of the subject.

Regarding claim 30, Djupesland discloses a gas supply unit (330) that is an exhalation breath actuatable unit (figure 8) which is fluidly connected to the mouthpiece (310) such as to be actuated on exhalation by the subject.

Regarding claim 31, Djupesland discloses a method of delivering substance (CO₂) to a nasal airway of a subject, comprising the steps of delivering substance to a nasal airway of a subject; exhaling through a mouthpiece (310) during delivery of substance to cause closure of the oropharyngeal velum of the subject (page 17, lines 15-25; and applying a varying pressure in the nasal airway of the subject (based on the exhalation of the subject which will inherently vary during the breathing cycle).

Regarding claim 33, Djupesland discloses the exhalation of a subject through the mouthpiece as the method of delivering pressure to the nasal airway. Since the pressure will inherently vary during the breathing cycle of a patient, the pressure in the nasal airway of the subject will inherently alternate the pressure in the nasal airway of the subject.

Regarding claim 35, Djupesland discloses a nasal delivery device for delivering substance to a nasal airway of a subject, with a mouthpiece (310) through which a subject in use exhales to cause closure of the oropharyngeal velum of the subject (See: page 17, lines 15-17); at least one delivery unit (330) for delivering substance to a nasal airway of the subject on exhalation the subject; and Alving teaches a gas supply unit (4) that can be connected to pumps 3A and 3B to alternately delivering and withdrawing a volume of gas through the nasal airway of the subject on exhalation by the subject, such as to cause entrained substance to be flushed in alternate directions there through.

Regarding claim 36, Djupesland discloses a method of delivering substance to a nasal airway of a subject, delivering substance to a nasal airway of a subject; and exhaling through a mouthpiece (310) during delivery of substance to cause closure of the oropharyngeal velum of the subject; and Alving teaches a method of delivering a substance using a ventilator that is connected to pumps 3A & 3B that can be used to alternately deliver and withdraw gas through the nasal airway of the subject to cause entrained substance to be flushed in alternate directions there through.

7. Claims 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Djupesland et al., (WO 00/51672), herein referred to as Djupesland '672.

Regarding claim 38, Djupesland '672 discloses an interface member (figure 9) for attachment to a nasal delivery device, comprising, as an integral element, at least one nosepiece (132) for fitting to a nostril of a subject and a mouthpiece (114) through which the subject in use exhales, wherein the mouthpiece includes a flexible member (116) which is deflectable on exhalation into the mouthpiece so as to trigger a substance supply unit (120) in the nasal delivery device, and wherein the integral element (132) is configured such that no part of the delivery device to which it is attached is exposed to the exhalation breath of the subject (it appears that the delivery device 110 in figure 9 is not exposed to exhalation breath of the subject; however, such a modification would be obvious to a skilled artisan given that figures 3 & 4 show that the nosepiece(s) and mouthpiece can be separable.

Regarding claim 39, Djupesland '672 discloses first (30) and second (40) nosepieces for fitting to respective nostrils of a subject.

Regarding claim 40, Djupesland '672 discloses an integral element that is a disposable element.

Regarding claim 41, Djupesland '672 discloses a mouthpiece comprises a tubular section (24) through which the subject in use exhales.

Regarding claim 42, Djupesland '672 discloses a mouthpiece that comprises a cavity (between 26 & 28) into which the subject in use exhales, with a part of the cavity being defined by the flexible member (28).

Regarding claim 43, Djupesland '672 discloses a flexible, resilient member (28).
See: page 17, line 22 - page 18, line 2.

Response to Arguments

8. Applicant's arguments filed 7/9/08 have been fully considered but they are not persuasive.

9. Regarding the nonstatutory double patenting rejection of claims 28 and 35 as being unpatentable over claim 6 of 6,715,485, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

10. Applicant's arguments with respect to the prior art rejections of claims 1, 3-16, 18-31, 33, 35-36, and 38-43 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **CLINTON OSTRUP** whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771